IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SCIELE PHARMA, INC. *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. 09-037 (RBK) (JS)
	)	
LUPIN LTD., *et al.*,	)	(CONSOLIDATED)
	)	
Defendants.	)	REDACTED VERSION
	)	

LUPIN DEFENDANTS' OPENING BRIEF IN SUPPORT OF THEIR MOTION TO BIFURCATE LIABILITY AND DAMAGES AND TO STAY DAMAGES DISCOVERY

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Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively "Lupin") submit this opening brief in support of their motion to bifurcate liability from damages in this matter and their motion to stay damages discovery pending resolution of liability issues. Lupin seeks this relief, which is frequently granted in patent cases such as this one, because the liability and damages issues are highly complex and do not overlap, separating them will avoid juror confusion and promote judicial efficiency, and the parties will not be prejudiced. Since the Court of Appeals for the Federal Circuit stayed the preliminary injunction barring Lupin from marketing its products, Lupin has resumed sales of its ANDA products and the Andrx plaintiffs have launched their authorized generic, complicating already complex damages issues. If the Court determines that liability and damages should be bifurcated, staying damages discovery will serve at least one of the purposes of bifurcation – to defer costly, and potentially unnecessary, fact and expert discovery and trial pending the resolution of liability issues.

STATEMENT OF FACTS

This complex patent litigation case involves four patents covering an extended release diabetes drug called Fortamet®[1] and Lupin's efforts to bring generic competition. (*See* D.I. 313.) Fortamet® is indicated as an adjunct to diet and exercise to lower blood glucose to improve glycemic control in adults with Type 2 diabetes. Plaintiff Andrx Labs is the assignee of the patents and holder of the New Drug Application by which the FDA granted approval for the sale of Fortamet®; plaintiff Sciele Pharma, Inc. (now known as Shionogi, Inc. and hereinafter "Shionogi") is licensed to sell Fortamet® in the United States. (*Id.*)

[1] U.S. Patent Nos. 6,099,859 ("the '859 patent"), 6,866,866 ("the '866 patent"), 6,495,162 ("the '162 patent"), and 6,790,459 ("the '459 patent") are listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") for Fortamet®. All four are at issue in this litigation; two in the Amended Complaint and two in Lupin's Counterclaims.

The '866 patent claims that its invention provides "[a] controlled release oral dosage form for the reduction of serum glucose levels in human patients with NIDDM, comprising an effective dose of metformin or a pharmaceutically acceptable salt thereof and a controlled-release carrier to control the release of said metformin or pharmaceutically acceptable salt thereof from said dosage form, said dosage form being suitable for providing once-a-day oral administration of the metformin or pharmaceutically acceptable salt thereof, wherein following oral administration of a single dose, the dosage form provides a mean time to maximum plasma concentration (T_{max}) of the metformin from 5.5 to 7.5 hours after administration following dinner." (D.I. 313-1.)

Lupin's noninfringement defense rests in part on the fact that its dosage form provides a mean time to maximum plasma concentration of the drug well over 7.5 hours after administration of a single dose following dinner. The record already contains two tests of Lupin's product – one a single dose administered after breakfast and the other a single dose administered after dinner – which show T_{max} well outside the claimed range. (D.I. 232, 233.) Shionogi's expert has submitted two declarations attacking Lupin's after-dinner test (contested by a declaration submitted by one of Lupin's experts) and extrapolating from certain data that a "proper" test would show that Lupin's product did infringe. (D.I. 210, 247.) The parties dispute the significance of the use of logarithmic scale graphs, testing protocols, the proper interpretation of pharmacokinetic data, gluceogenesis, and additional topics relating to pharmacokinetic parameters, biopharmaceutics, bioavailability, and bioequivalence. (*Compare* D.I. 233 *with* D.I. 210.) The evidence submitted to the jury on this one limitation alone will involve extensive scientific and technical expert testimony, charts of test data, arguments about the statistical significance of test findings, physiology, pharmacokinetics, and the like.

Other claims of the '866 patent involve dissolution data. (D.I. 313-1.) The record contains conflicting test results concerning the dissolution profile of Lupin's ANDA product, and additional expert testimony involving different scientific and technological issues will be advanced by both parties with respect to these claims.

The '859 patent presents different technologies and scientific issues for the jury to grapple with. That patent claims, among other things, "[a] controlled release pharmaceutical tablet" which includes "a semipermeable membrane coating covering said core wherein the membrane is permeable to the passage of water and biological fluids and is impermeable to the passage of the antihyperglycemic drug wherein said coating comprises 50-99% of a polymer; 0-40% of a flux enhancer and 0-25% of a plasticizer" and "at least one passageway in the semipermeable membrane for the release of the antihyperglycemic drug." (D.I. 313-1.) As an example, the parties dispute the nature of the membrane in Lupin's products. The expert testimony on these issues will involve other areas of chemistry and science, such as those involving polymers and membrane function. The parties are likely to introduce competing test evidence and interpretations concerning, among other things, the mechanisms by which the active ingredient is released from the core of Lupin's products, which will involve scientific, chemical and pharmaceutical concepts such as osmosis, osmotic release mechanisms, swellable polymers, expanding matrices in the core of pharmaceutical dosage forms, *in vivo* as opposed to *in vitro* behavior of pharmaceutical dosage forms, and the like.[2]

In addition to the infringement questions, the jury will be confronted with Lupin's defense that both patents are invalid as obvious in view of prior art. The jury will hear evidence concerning the existence and meaning of other patents and articles involving the issues

[2] The issues involved in the '859 patent are not as fully developed as those of the '866 patent, since the preliminary injunction motion focused on the '866 patent. (*See* D.I. 205.)

mentioned above, as well as additional issues, such as those going to the knowledge of persons of skill in the art and their motivation to combine teachings from prior art. With respect to the '866 patent, for instance, one of the disputes is whether a person of skill would have been motivated to combine the disclosure of the claimed T_{max} range in one prior art, Timmins, WO 99/47128 ("Timmins"), with the other aspects of the '866 claimed invention disclosed in another prior art, Cheng WO 99/47125 ("Cheng").[3] Plaintiffs' arguments include a claimed distinction based on whether the two pieces of prior art both involve bioavailability of metformin under similar circumstances, and Lupin's response relies in part on the disclosed test data.

Even before the jury reaches the question of motivation, it will need to understand the science and information disclosed in the prior art and will need to determine the level of knowledge and skill held by a person of skill in the art. Lupin's obviousness defense is not restricted to these two pieces of prior art; its contentions list numerous others.

The issues with respect to the obviousness of the '859 patent involve different prior art. For example, the obviousness challenge to the '859 patent includes, among other things, evidence concerning the osmotic release mechanism disclosed in the Alza patents referenced in the '859 patent, the significance of a membrane with a passageway, and whether there are differences between the claimed invention and other prior art dosage formulations which appear also to disclose membranes with at least one passageway for the release of the active ingredient.

The '162 and '459 patents raise similar issues to the '859 and '866 patents, but have subtle differences that the jury may need to grasp.

[3] To add to the complexity, plaintiffs do not concede that Cheng discloses all of the other attributes of the invention. For instance, they claim that the dissolution profiles in Cheng are different from those in the '866 patent. Lupin counters that the dissolution profiles overlap, which is sufficient to show obviousness under the relevant law.

The issues involving damages are no less complex, although the science involved lies more in the areas of statistics, mathematics, and accounting than chemistry, pharmacokinetics, and pharmacology. In support of their efforts to discover Lupin's confidential commercial information, plaintiffs submitted a declaration from an expert detailing the complexity of damages discovery and the extensive information required in the usual patent case. (D.I. 389-1.) In opposition, Lupin submits a declaration from an economics expert with extensive experience not only in patent infringement litigation in general but in Hatch-Waxman litigation in particular. (D.I. 414.)

The jury will be asked to understand damages issues which might include market demand for Fortamet®, the market for other metformin products, including other extended release products, Shionogi's marketing efforts, the significance of Shionogi's decision to stop promotional activities, the unique aspects of the generic pharmaceutical market, prescription-writing practices, the generic substitution regulations, formulary positions, the size of the market and reasons for possible market expansion, the calculation of Shionogi's profits from its sales, the license arrangements between Shionogi and Andrx and how that influenced sales, Shionogi's pricing practices including the impact of its price increases, Shionogi's claims that it was forced to award discounts, and the scope and results of a hypothetical negotiation of a reasonable royalty.[4] Since Andrx launched its authorized generic product, the jury may also need to consider the effect of another generic on Shionogi's claims for damages. If Mylan, the defendant in the consolidated case, also goes on the market this summer, the damages picture will become even more complex.

[4] These are many of the issues which arise in Hatch-Waxman or pharmaceutical damages cases. While Lupin does not concede that all of them pertain to this case, if plaintiffs disagree, that question itself may need to be submitted to the jury to determine.

PROCEDURAL HISTORY

Lupin notified plaintiffs on December 3, 2008, that it had filed its ANDA to manufacture and sell a generic version of Fortamet® including a paragraph IV certification that its products would not infringe a valid patent. Shionogi filed its patent infringement suit against Lupin on January 15, 2009, claiming infringement of both the '859 and '866 patents. (D.I. 1.) Lupin counterclaimed for declaratory judgment that it did not infringe valid claims of the '162 or '459 patents. (D.I. 8.) Approximately one year later, Shionogi filed a patent infringement suit against Mylan, Inc. and Mylan Pharmaceuticals Inc., in response to their ANDA for a generic version of Fortamet®. The two actions were consolidated for pre-trial purposes. (D.I. 48)

The FDA gave final approval to Lupin's ANDA and its label on June 29, 2011. (D.I. 313.) [redacted]

On September 30, 2011, Lupin began marketing its ANDA products. Shionogi moved for a preliminary injunction and recall on October 12, 2011. The injunction was granted by a December 6 decision and order; the recall was denied. (D.I. 279.)

On January 31, 2012, in accordance with the scheduling order, plaintiffs amended their complaint as of right to include a claim for money damages, based (according to their amended initial disclosures) on lost profits, price erosion, reasonable royalties, and consequential harm including increased overhead, increased costs of research and development, and harm to Shionogi's work force. (*See* D.I. 313.)

The Federal Circuit granted Lupin's motion for an expedited briefing schedule on its appeal from the order granting the preliminary injunction.[5] Oral argument was held the afternoon of April 18, 2012. Less than two hours after the completion of the argument, the appellate court stayed the preliminary injunction and Lupin returned to the market. Andrx also then began to sell an authorized generic Fortamet® product, pursuant to its licensing agreement with Shionogi.

Damages discovery is just beginning. While some documents have been produced, damages have only recently become part of the case. Nevertheless, as noted above, pending before this Court are two difficult discovery disputes that will require this Court to balance plaintiffs' claimed need for Lupin's highly sensitive and confidential information against Lupin's argument that disclosure of the information, while barely, if at all, relevant, will cause Lupin commercial harm.

Lupin's counsel approached plaintiffs' counsel to ask whether they would consent to bifurcate damages and liability and suggested that the parties meet-and-confer about the issue. Shionogi's counsel responded that it opposed bifurcation and no meet-and-confer was necessary.

ARGUMENT

As is frequently done in pharmaceutical (and other) patent cases, the liability and damages phases should be bifurcated because of the complexity of the liability and damages issues, which do not overlap. Keeping the issues together would result in a lengthy, complicated trial that likely would cause juror confusion and would waste judicial resources, since a liability

[5] Earlier, the Federal Circuit vacated the preliminary injunction and remanded for the Court to reconsider its rejection of Lupin's obviousness defense. This Court reinstated the injunction with an expanded explanation of its rationale on February 23, 2012. Lupin filed its notice of appeal the same day.

finding for Lupin would obviate the need for a trial on damages entirely. Separating the two cases will not prejudice plaintiffs.

Courts have broad discretion to bifurcate separate issues or claims "[f]or convenience, to avoid prejudice, or to expedite and economize." FED. R. CIV. P. 42(b). Courts within this Circuit have found patent cases particularly well-suited for bifurcation. *See, e.g., Dutch Branch of Streamserve Dev. AB v. Exstream Software, LLC*, No. 08-343-SLR, 2009 U.S. Dist. LEXIS 76006, at * 2 (D. Del. Aug. 26, 2009) (bifurcating damages and willfulness); *Medpointe Healthcare, Inc. v. Hi-Tech Pharmacal Co*., No. 03-5550, 2007 U.S. Dist. LEXIS 4652, at *19 (D.N.J. Jan. 22, 2007) (bifurcating liability and damages); *Ciena Corp. v. Corvis Corp*., 210 F.R.D 519, 521 (D. Del. 2002) (trifurcating liability, invalidity, and damages); *Princeton Biochemicals, Inc. v. Beckman Instruments, Inc.*, 180 F.R.D. 254, 261 (D.N.J. 1997) (bifurcating damages and willfulness), *aff'd*, 411 F.3d 1332 (Fed. Cir. 2005).

When exercising their broad discretion under Rule 42(b), courts "consider whether bifurcation will avoid prejudice, conserve judicial resources, and enhance juror comprehension of the issues presented in the case." *Ciena Corp.,* 210 F.R.D. at 520 (citing *Union Carbide Corp. v. Montell N.V.,* 28 F. Supp. 2d 833, 837 (S.D.N.Y. 1998)). "'[T]he major consideration is directed toward the choice most likely to result in a just final disposition of the litigation.'" *Ciena Corp.,* 210 F.R.D. at 520-21 (citing *In re Innotron Diagnostics,* 800 F.2d 1077, 1084 (Fed. Cir. 1986)). The judicial efficiency and economy resulting from bifurcation is another consideration which supports the procedure in complex patent cases.

"'[E]xperienced judges use bifurcation and trifurcation both to simplify the issues in patent cases and to maintain manageability of the volume and complexity of the evidence presented to a jury.'" *Enzo Life Scis., Inc. v. Digene Corp.,* No. 02-212-JJF, 2003 U.S. Dist.

LEXIS 10202, at *15 (D. Del. June 10, 2003) (citation omitted). *See also Medpointe Healthcare,* 2007 U.S. Dist. LEXIS 4652, at *19; *Ricoh Co. v. Katun Corp.*, No. 03-261, 2005 U.S. Dist. LEXIS 46493, at *3 (D.N.J. July 14, 2005) (bifurcating antitrust counterclaims). Ten years ago, then-Judge Farnan of the District of Delaware noted that "bifurcation of complex patent trials has become common." *Ciena Corp.,* 210 F.R.D. at 521. He relied on his extensive personal experience with patent jury trials and "determined that the use of alternative trial procedures could assist juries in obtaining a better understanding of the legal issues they are called upon to decide." *Id.* Indeed, Judge Farnan held that the damages case would not be tried until after the liability appeals were completed. *Id.* Seven years later, Judge Robinson, also of the District of Delaware, agreed that "bifurcation is appropriate, if not necessary, in all but exceptional patent cases." *Dutch Branch*, 2009 U.S. Dist. LEXIS 76006 at * 2. She agreed that "the burden imposed on a jury in a patent trial is extraordinary," and "bifurcation promotes the just and efficient resolution" of the case. *Id.* at *2-*3. In fact, Judge Robinson's form scheduling order bifurcates damages in all patent cases. *See* http://www.ded.uscourts.gov/sites/default/files/Chambers/SLR/Forms/Sched-Order-Patent_04-03-12.pdf.

In a much-cited Delaware case, *Smith v. Alyeska Pipeline Service Co.,* the court summarized the benefits of separate trials on liability and damages:

> In the normal case separate trial of issues is seldom required, but in a patent infringement suit considerations exist which suggest that efficient judicial administration would be served by separate trials on the issues of liability and damages. The trial of the damages question in such a suit is often difficult and expensive, while being easily severed from the trial of the questions of validity and infringement of the patent. A preliminary finding on the question of liability may well make unnecessary the damages inquiry, and thus result in substantial saving of time of the Court and counsel and reduction of expense to the parties. Moreover, separate trial of the issue of liability may present counsel the opportunity to obtain final

> settlement of that issue or appeal without having reached the often time-consuming and difficult damages question.[6]

538 F. Supp. 977, 982-83 (D. Del. 1982) (quoting *Swofford v. B&W, Inc.,* 34 F.R.D. 15, 19-20 (S.D. Texas 1963) (internal citations omitted)), *aff'd*, 758 F.2d 668 (Fed. Cir. 1984).

The judges in the District of New Jersey agree with the Delaware judiciary that patent cases, such as the instant case, should be bifurcated. *See, e.g., Wyeth v. Abbott Labs.,* No. 08-230, 2010 U.S. Dist. LEXIS 116921, at *5 (D.N.J. Nov. 3, 2010) ("Bifurcation will allow the jury to focus on the complicated issues of infringement and validity without simultaneously having to consider evidence relating to various theories of damages."); *Ortho-Mcneil v. Teva Pharms*. *USA,* No. 02-2794, 2003 U.S. Dist. LEXIS 27901, at *8 (D.N.J. Jan. 28, 2003) (bifurcating damages and liability although "issues are not necessarily complex" because the issues of liability and damages are "two distinct causes of action"); *Princeton Biochemicals,* 180 F.R.D. at 256 ("[C]oncerns of prejudice, complexity, expedition, and judicial economy are particularly significant in patent cases.").[7]

Other districts agree. *See, e.g., Novopharm Ltd. v. Torpharm, Inc.*, 181 F.R.D. 308, 310 (E.D.N.C. 1998) ("Patent cases are often uniquely amenable to bifurcation because of the complex nature of the damages determination and the extensive discovery that is often necessary to prove the nature and extent of those damages."); *B. Braun Med.. v. Abbott Lab.*, No. 93-3883,

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[6] The *Smith* court noted a little later in the opinion that "if any of the liability issues are resolved in [defendants'] favor, no further trial will be necessary. On the other hand, if the liability issues are resolved in [plaintiff's] favor, then [defendants] might very well settle the damages to avoid the lengthy trial." 538 F. Supp. at 984.

[7] Of course, in some situations, the facts do not warrant bifurcation, even in a patent case. *See, e.g., Sepracor Inc. v. Dey L.P.,* No. 06-113-JJF, 2010 U.S. Dist. LEXIS 71955, at *6-*9 (D. Del. July 15, 2010) (finding that on the facts of that case and given the overlap of evidence, bifurcation was not necessary to avoid confusion at jury trial); *Arendi Holding Ltd. v. Microsoft Corp.,* No. 09-119-JJF, 2009 U.S. Dist. LEXIS 100507, at *4 (D. Del. Oct. 27, 2009) (no bifurcation given previous trial of similar technology which had been bifurcated and fast-track schedule).

1994 U.S. Dist. LEXIS 12104, at *3 (E.D. Pa. Aug. 24, 1994) ("The Court finds it likely that the jury will become confused if required to consume this amount of information at one time."); *Avia Group Int'l, Inc. v. Nike, Inc*., No. 91-326-JU, 1991 U.S. Dist. LEXIS 20492, *3-*9 (D. Or. Sept. 17, 1991) (bifurcating liability, damages, enhanced damages and attorneys' fees and staying discovery related to willfulness).

This case clearly falls into the category of a complex patent infringement case, with numerous complicated issues, in which bifurcation would promote judicial economy and further the likelihood of a just result. As in *Princeton Biochemicals*, the jury in this case will "likely be required to process volumes of exhibits, including diagrams, drawings, documents, models, as well as trial testimony, on the issue of liability alone." 180 F.R.D. at 258. The liability case should be separated from the damages case because "the complexity of the liability issues as well as the resulting potential threat of prejudice due to jury confusion, present a controversy ripe for bifurcation . . . . Even plaintiff's most simplistic assessment of the underlying technology and the liability issues in question are likely to be confusing to a jury, unsophisticated in the area of intellectual property." *Id.* at 257.

On the preliminary injunction motion alone, which involved just one aspect of one patent, the parties submitted nine declarations from seven experts covering areas of pharmacology, pharmacokinetics, formulation, biopharmaceutics, bioavailability, and bioequivalence, among other things.[8] Not surprisingly, the experts disagreed with each other, leading Judge Kugler to find that he was unable to resolve the "battle of experts" on the written record. (D.I. 279.) Resolution of these battles has the potential to be complex and involve evaluation of technical and scientific issues beyond the experience of most jurors. *See Ricoh Co.,* 2005 U.S. Dist.

[8] Lupin submitted an additional expert declaration concerning the membrane in its formulation.

LEXIS 46493 at *4 ("[P]atent cases in general, involve matters of fact and issues of law that are not as intuitive to the average reasonable juror as more common actions"). The jury will be confronted with questions involving both infringement and invalidity, looking not only to these patents, but also to scientific articles and other patents which comprise the prior art.

Unlike in *Sepracor,* 2010 U.S. Dist. LEXIS 71955, liability and damages issues do not overlap in this case. The liability issues turn on the science of the patents, the prior art, and the accused product. *See Avia Group Int'l Inc.*, 1991 U.S. Dist. LEXIS 20492 at *5 (stating liability in a patent case focuses on "the specifics of the invention, the validity of the patent, and the structure and operation of the allegedly infringing product"). In contrast, the damages case will focus on financial and economic evidence necessary for plaintiffs to meet their burden of proof. *See id.* (stating damages issues require "proof of sales, costing factors, profit levels and offsetting costs"). Simply put, the lack of overlap between liability and damages in this case will likely result in little to no duplication of effort by the parties if the trial is bifurcated. *See Smith,* 538 F. Supp. at 983 (quoting the Fifth Circuit affirmance of *Swofford* that it could "not think of an instance in a patent action where the damage[s] issue is so interwoven with the other issues that it (could) not be submitted to a jury independently of the others without confusion and uncertainty.").[9] Including liability and damages in the same proceeding will introduce another array of competing experts, analyses, and approaches, again relying on technical fields outside

[9] Lupin's obviousness defense potentially raises issues with respect to commercial success, but this should not preclude bifurcation. *See*, *e.g.*, *Princeton Biochemicals*, 180 F.R.D. at 259 ("the question of commercial success is not ordinarily determined by a detailed analysis of exhaustive and intricate financial data, such as is required for proof of damages") (internal quotation marks omitted)); *In re Recombinant DNA Tech. Patent & Contract Litig.*, 30 U.S.P.Q. 2d (BNA) 1881, 1900 (S.D. Ind. 1994) ("[A]ny possible overlap in evidence [regarding commercial success] will be insubstantial.").

the daily knowledge of most jurors. To add to the complexity, the jurors will have to consider the effect of sales of Andrx's authorized generic.

The jury should be allowed to focus on the technical issues posed by the liability case without being burdened by the complex financial issues posed by plaintiffs' damages theories. "The information the jury must comprehend to determine the liability issues alone is burdensome. Admitting financial data that also is potentially time consuming and complex could make that burden unmanageable." *In re Recombinant DNA*, 30 U.S.P.Q. 2d (BNA) at 1899. As the court recognized in *Princeton Biochemicals*, "Federal precedent suggests that the entire damages phase of patent litigation could be severed from issues of liability, upon a finding that the damages issues are complicated and extensive evidence would be necessary on these issues." 180 F.R.D. at 256.

"Consideration of the damages from any liability the jury finds could be complex, involved and time-consuming." *Novopharm,* 181 F.R.D. at 311 (reciting the complexity of damages calculations based on reasonable royalty and lost profits). As Judge Robinson explained, "[J]uries are tasked with resolving complex technical issues regarding infringement and invalidity, many times with respect to multiple patents and/or multiple prior art references. Absent bifurcation, jurors then are expected to understand the commercial complexities of the relevant market (or, even more impenetrable, the commercial complexities of the hypothetical market) in order to determine the economic consequences of their liability decisions." *Dutch Branch,* 2009 U.S. LEXIS 76006 at *2-*3. This may be why so many courts have concluded "[t]hat the production and synthesis of these materials may ultimately become unnecessary militates in favor of bifurcating the trial of this suit." *Novopharm,* 181 F.R.D. at 311.

Once liability and damages are bifurcated for trial, it follows that damages discovery should be stayed to reap the full benefits of judicial efficiency and economy, as well as to protect the parties from unnecessary expenditure of resources. As Judge Robinson noted, "[I]n my experience, discovery disputes related to document production on damages and the *Daubert* motion practice related to damages experts are a drain on scarce judicial resources." *Dutch Branch*, 2009 U.S. Dist. LEXIS 76006 at *2.

If damages are bifurcated, there is "no reason to order defendant to expend tremendous efforts and funds to produce volumes of documents [and expert reports] concerning issues of damages and willfulness prior to a finding of liability." *Princeton Biochemicals*, 180 F.R.D. at 261 (noting several courts which "as matter of course, stayed discovery of the bifurcated issues"). *See also, e.g., Wyeth,* 2010 U.S. Dist. LEXIS 116921 at *6 ("Having found that bifurcation is warranted, the Court finds that a stay of discovery with respect to damages is appropriate"); *Ortho-McNeil,* 2003 U.S. Dist. LEXIS 27901 at *10 (conducting discovery on bifurcated issue "is premature at this point"); *Novopharm*, 181 F.R.D. at 312 (staying damages discovery pending resolution of liability) ("One of the purposes of bifurcation under Rule 42(b) is to defer costly discovery and trial preparation costs pending the resolution of preliminary liability issues.").

The same logic applies equally here. In light of the expense and effort the parties, not to mention the Court, would be compelled to expend on damages-related discovery prior to a finding of liability, and given that no fact depositions or expert discovery has occurred relating to damages, discovery on damages should be stayed pending resolution of the liability issues.

CONCLUSION

For the foregoing reasons, Lupin respectfully requests that the Court order that all issues relating to damages be tried, if necessary, separately from and after the liability trial and appeal in this case. Lupin also requests that the Court stay any discovery regarding damages issues until after a final determination of liability.

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